OCT 1 4 2003

K031769

EEMSO, INC.

510 (K) Summary

General Information on Submitter

EEMSO, Inc.
6120 peeler Street
Dallas, Texas 75235
Telephone: (214) 956-0077
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II General Information on Device

Proprietary Name:	E-STRIP
Common Name:	Iontophoretic Treatment System
Classification:	Iontophoresis Device 21 C.F.R. 890.5525 (b)

III Predicate Devices

Iomed Phoresor II Model PM 700	K872040
With Trans Q 2 electrodes	K914264
Life-Tech Iontophor II Model 6111 PM/DX	????????
With Meditrode electrodes	
Ionto Patch	K992708

IV Device Description

The E-STRIP is an active; self- contained Iontophoretic Drug Delivery System. An Integrated battery mechanism within the butterfly-designed soft electrode provides the E-STRIP with the capacity to deliver safe and complete iontophoresis therapy. The delivery rate of medicine is determined by applied voltage, skin resistance, and Conductivity of the medication/ saline solution.

V Intended Uses

The E-STRIP device is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes.

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VI Technological Characteristics of the Device Compared to Predicate Devices

The technological characteristics of the E-STRIP are similar to those of the listed Predicate devices. As the source of current, the 1.55 VDC, 22 MAH (1320 mA-Minute) internal battery drives both positive and negative charged drug molecules Transdermally. Compared to traditional iontophoresis therapy, which requires a Current-generating device, lead wires and multiple electrode patches, the E-STRIP is Self-sustaining.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 2003

EEMSO, Inc.
C/o Mr. Larry R. Pilot
McKenna Long & Aldridge LLP
1900 K Street, NW
Washington, DC 20006

Re: K031769
E-STRIP
Regulatory Class: III
Product Code: EGJ
Dated: June 9, 2003
Received: June 9, 2003

Dear Mr. Pilot

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the device as described below. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class II. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class III (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994, and the enclosed Federal Register, dated August 22, 2000.

If you have any questions regarding this letter, you may contact:

Kevin Lee, M.D.
Food and Drug Administration
Center for Devices and Radiological Health
Division of General, Restorative and Neurological Devices
9200 Corporate Boulevard (HFZ-410)
Rockville, Maryland 20850
(301) 594-1296

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (301) 594 – 4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may

obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

EMSO, INC.

Indications For Use Statement

The E-STRIP device is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031769

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